

URODYNAMIC PRESSURE SENSOR

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Introduction

A widespread method for measuring the closing pressure profile along the female urethra is to insert a sensor into the bladder and withdraw it at a controlled rate such that time translates into distance and sensor output or pressure is the dependent variable. A second sensor element, located distally from the first, remains in the bladder to provide a reference pressure. By synchronizing the speed of an analog strip chart recorder with the withdrawal rate of the sensor, one obtains a measure of the pressure profile along the urethral length. Two aspects of this method are controversial, first, because the sensor area is quite small, it includes only a relatively small portion of the total circumference giving rise to questions regarding circumferential sensitivity, and, second, as the sensor is being withdrawn, transient events, coughs, muscular impulses, etc., cannot be duplicated over time in order to examine the response of the total organ to a single event. With these concerns in mind, a transducer system has been developed which provides up to five sensors within the functional length of the urethra, addressing the simultaneity issue, and where each sensor has an axial symmetry, thereby addressing the circumferential sensitivity issue. Three sensors have been constructed and one of them has been subjected to approximately eight hours of use in a clinical setting during which 576 dynamic data points were obtained. The complete instrument system including the signal conditioning electronics, data acquisition unit, and the computer with its display and printer is shown in Figure 1. The technical details of the catheter sensor system itself is described in this paper.

Transducer System Design

Requirements:

The requirement for the measurement system, as originally stated, was to be able to measure the closing forces along the continuous female urethra, to include an internal lumen for infusion or venting of the bladder, be very flexible and less than three-French in outside diameter, sense pressures in the range of 10 to 200 centimeters of water, and to be integrated into a computer system to facilitate the data reduction process. Continuous sensing of the closing forces within the functional length of the urethra was deemed impractical and was changed to "as many discrete measurement points as is practical." This translated into a cylindrical transducer structure having five sensing areas, each area approximately 0.2 inches long and within a length of one and one-half inches, approximately one-eighth inch in diameter, hollow, in order to contain an internal lumen, and a sixth sensing element located approximately one and one-half inches from the others. The resulting transducer system, without its protective sheath, is shown in Figure 2. Here one sees the five closely spaced sensor elements and a sixth element located some distance from the others to be always in the bladder and thus provide a reference. With this arrangement, discrete but simultaneous measurements are obtained throughout the urethra. Figure 3 is an enlarged view of one sensor element and is seen to be shaped like a "C". As pressure is applied around the circumference of this element displacement of the two halves (tending to close the longitudinal gap) results causing bending stresses to appear in the spine portion. These stresses cause minute deformations in the outer fibers of the metal which are then sensed with strain gages.

Sensor Design

Each sensor element is cylindrical, nominally 0.120" diameter by 0.118" long by 0.004" thick; has a slot approximately 0.010" wide cut in the axial direction; and has slots machined transverse to the axis, leaving approximately 0.040" of circumferential area to act as a spine. To obtain a quantitative relationship for the sensor, first convert pressure in centimeters of water to pounds per square inch:

$$P_{\text{psi}} = 0.014215 \times P_{\text{cm-H}_2\text{O}}$$

Therefore:

$$P_{\text{min}} = 0.142 \text{ psi} \quad \text{and} \quad P_{\text{max}} = 2.843 \text{ psi}$$

This distributed pressure acting over the movable portion of the circumference can be represented as an equivalent force acting at the midpoint of each segment which then produces a bending moment at the root or spine. Young's modulus is then used to relate stress to strain as follows:

$F = P \times A$	$P = \text{Pressure and } A = \text{Area}$
$M = F \times L/2$	$L = \text{Length and } M = \text{Root Bending Moment}$
$s = \frac{Mc}{I}$	$s = \text{stress, } c = \text{distance to outer fiber}$
	$I = \text{Moment of area of sensor segment}$
$\epsilon = s/E$	$\epsilon = \text{strain, } E = \text{Young's Modulus}$

Combining the applicable constants and values gives the following expression for strain as a function of pressure tending to close or compress the sensor:

$$\epsilon = 2.378 \times 10^{-6} \times P_{\text{cm}}$$

This being the expression for mechanical strain at the root of the movable section, strain gages are placed in this area to convert the minute mechanical deformations into electrical signals proportional to strain. At the minimum pressures anticipated, the strains are very small, and every effort must be made to minimize extraneous effects and to enhance the signal at the point of inception. This is accomplished by placing a full, active four-arm Wheatstone bridge at the measurement site. In this manner, two gages are mounted in each half of the "C" section, one mounted in the circumferential direction or maximum strain direction, and the other mounted normal to the first. Connected in this fashion, two gages sense the compressive strains present on the inner surface; and two gages, mounted at 90 degrees to the others, measure the Poisson's ratio strains. Significantly, all gages see the same environment which minimizes the effects of extraneous inputs.

The above analysis must be qualified somewhat, acknowledging the finite size of the strain gages and the presence of an elastomeric sheath surrounding the final sensor. Finite size of the gages means that the entire gage does not see the level of strain as shown above, but rather an average over its sensitive area; and the sheath is a non-linear elastic member spanning the measuring section which effectively presents some load-carrying capacity in parallel with the measuring "C" sections. The non-linear effects are assumed small at this point, and the gage installation effects are accommodated through calibration.

The usable output voltage or signal from the strain gage bridge is dependent upon the gage factor, the number of active bridge arms, and the excitation or bridge voltage. The present configuration consists of two active arms (plus two Poisson's ratio arms) with a nominal gage factor of two. Semiconductor strain gages exhibit gage factors on the order of 120, sixty times that of the foil gages used, which would significantly improve the signal-to-noise ratio; however, semiconductor gages require a relatively flat surface because of their brittleness. In this application, the tight radius of curvature precludes their use. Utilizing a large, bridge excitation voltage will also maximize the output and signal-to-noise-ratio; however, one must always be cognizant of the self heating of the gage caused by I^2R losses which introduces long-term drift of the system. Combining all the applicable factors, one arrives at the following expression for sensor output voltage:

$$\text{Output Voltage} = 4 \times \text{Bridge Voltage} \times \epsilon$$

which for a bridge excitation voltage equal to 2 Volts,

$$\text{Output Voltage} = 19 \times 10^{-6} P_{cm}$$

From this it is seen that the range of output voltages from the transducer is from approximately 190 to 3800 μ volts. Most acquisition or display devices require signals in the ± 2.5 volt range. Thus it is obvious that a significant amount of amplification or gain in the system is required.

Signal Conditioning

Signal conditioning consists of individual channel signal isolation, offset zero and gain adjustments, and low pass filtering of the data. The data is passed through isolation amplifiers and filtered to pass frequencies below 150 Hertz. The overall gain is adjustable and typically on the order of 250 to 300 making full scale signals approximately 1 Volt. The data is then passed to a sampling and analog-to-digital conversion subsystem where the data is quantized to 12-bit precision, and 250 samples from each channel are accumulated at a 100 samples-per-second rate. These records are then stored on disk for post test analysis.

Transducer Calibration

A hydrostatic calibrator was constructed which consisted of a sealed chamber in which the catheter could be horizontally placed and water allowed to enter, expelling any air from the chamber. The chamber is connected via a flexible hose to an accumulator which can be raised or lowered to change the pressure in the chamber. Once the air is completely expelled from the system, the pressure is allowed to equilibrate with the level of water in the accumulator adjusted to the level of the catheter. At this point, the channels are adjusted for zero output after which the accumulator is raised to 100 centimeters and the gain adjusted to some convenient value. Iteration between the zero level and the 100cm level a few times and adjusting the zero and gain controls at each end will remove any interactions, and a convenient conversion factor, say 200 cm/volt, is established. By adjusting the height of the water column in a definite sequence, one can determine the drift, hysteresis, and linearity. Because pressure is a scalar quantity, it exerts the same influence in all directions making a good calibration of the instrument to measure circumferential closing forces.

System Output

As stated previously, the data is accumulated on a hard disk in the computer making it possible to perform any number of analysis procedures. Figures 4a and 4b illustrate two different formats that were used up to this point. Figure 4a includes test parameter and system information as well as a plot of the actual time history values, whereas figure 4b is merely a full-page representation of the particular time history. The two figures are from two different subjects, and one can see distinct differences in the shape of the time history.

CONCLUDING REMARKS

Based on the needs expressed at the outset, it is concluded that a sensor system has been developed which captures the essence of the requirements. Simultaneous measurement, at several discrete locations within the urethra, and insensitive, though not yet proven absolutely, to circumferential positioning of the catheter are features of the design. As a result of the clinical testing, a new catheter has been fabricated which is physically shorter and has the segments positioned closer together. This allows more sensor elements to be positioned within the effective length of the urethra, potentially four of the five as opposed to three for functionally shorter urethral lengths. Previously, the medical specialist was interested primarily in the amplitude at the respective element location and its ratio to the bladder pressure. With the new sensor and the associated data acquisition and display capability, not only amplitudes but also shape, rise and fall times, and muscular response propagation times are new parameters upon which diagnostic evaluations can be made.

ORIGINAL PAGE
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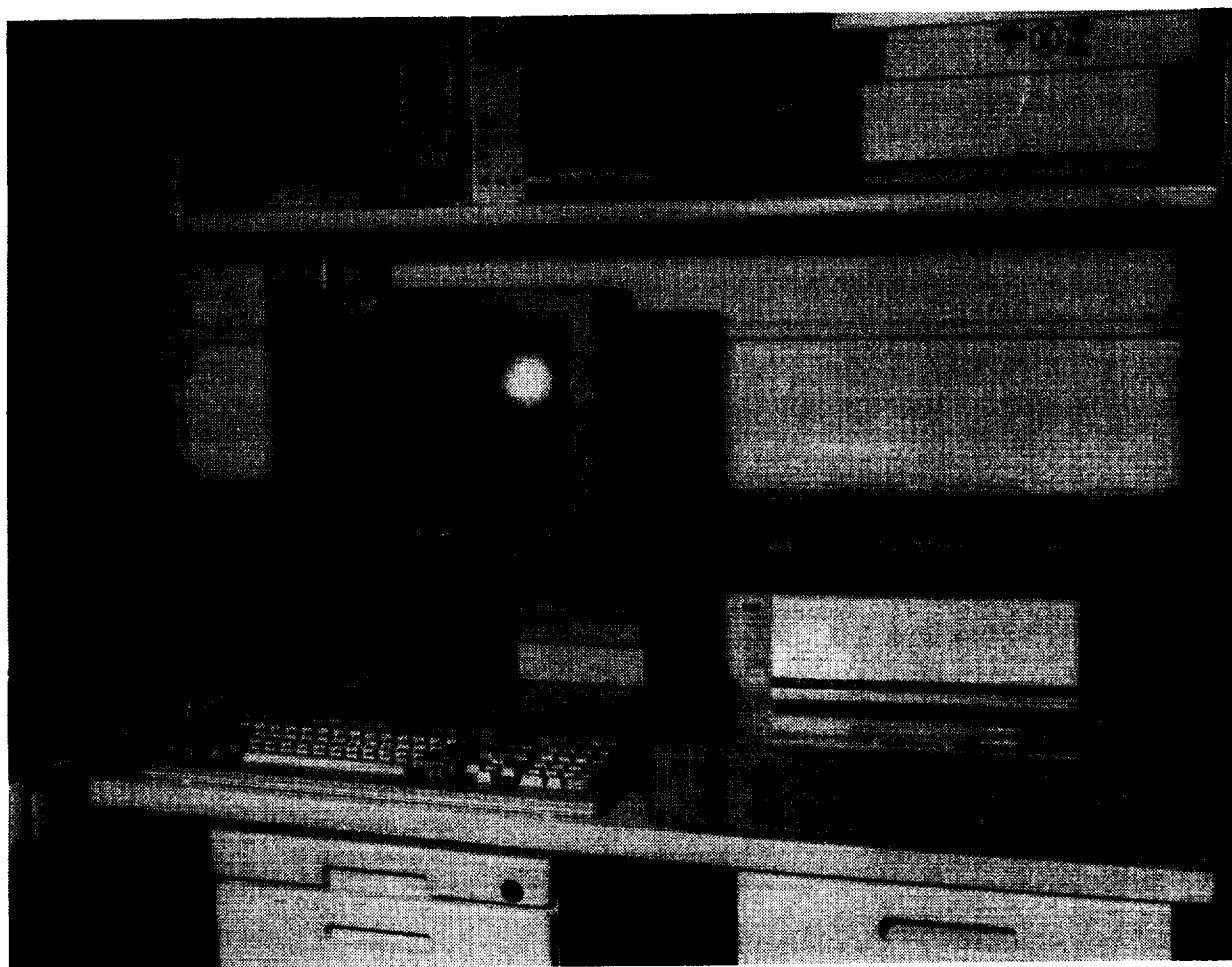


Figure 1: Signal Conditioning and Data Acquisition Instrumentation.

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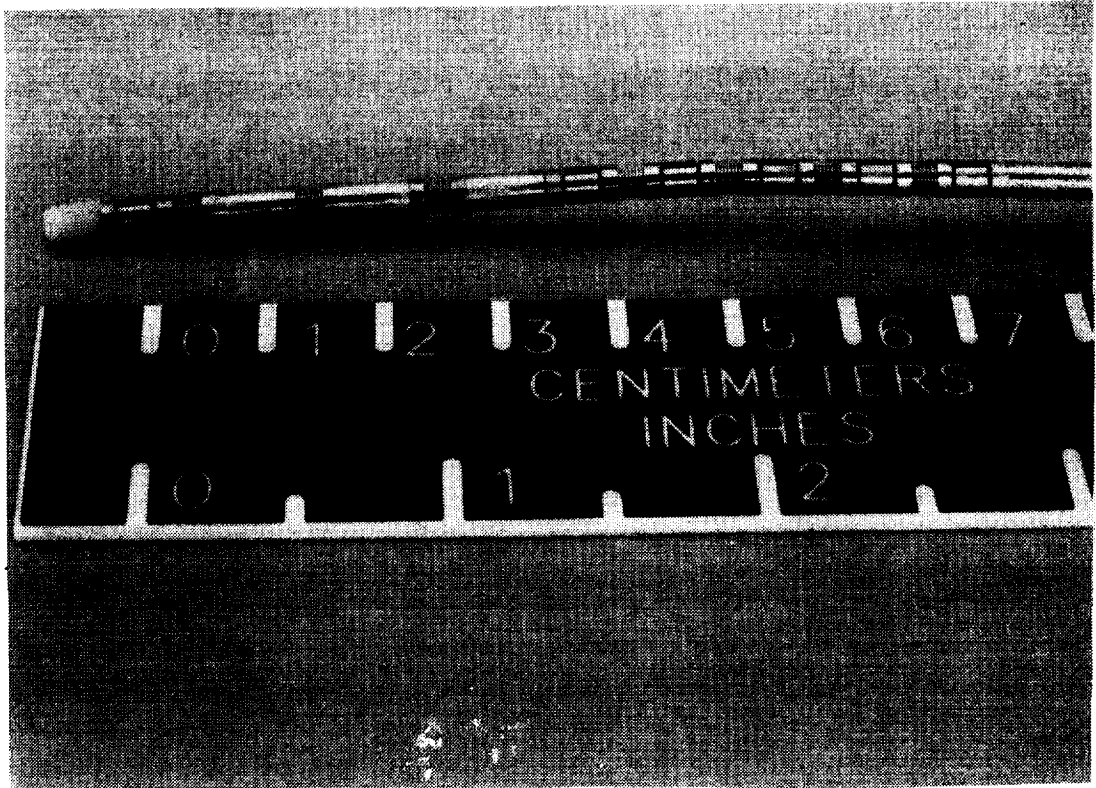


Figure 2: Six Element Catheter without Sheath

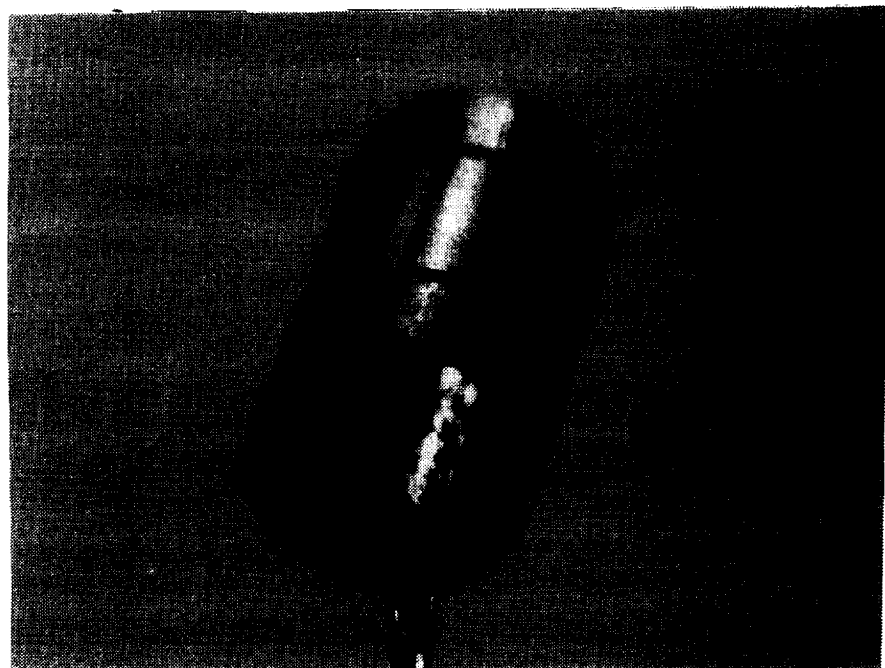


Figure 3: Enlarged View of Single Element

Datafile Name:	Unspecified
Version Number:	0
Signal Name:	Unspecified
Date Acquired:	11-23-1988
Time Acquired:	9:09:58.50
Vert Units:	Pressure
Horiz Units:	Secs
Num. Samples:	250

Sample Rate:	100
Maximum:	192.796882
Minimum:	89.987793
Comments:	Signal Generated in Analysis

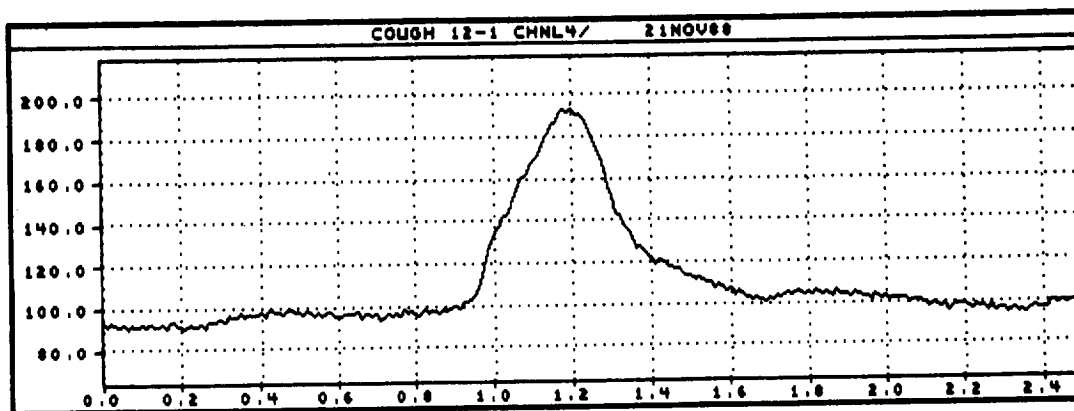


Figure 4a: Output Display, Format No. 1

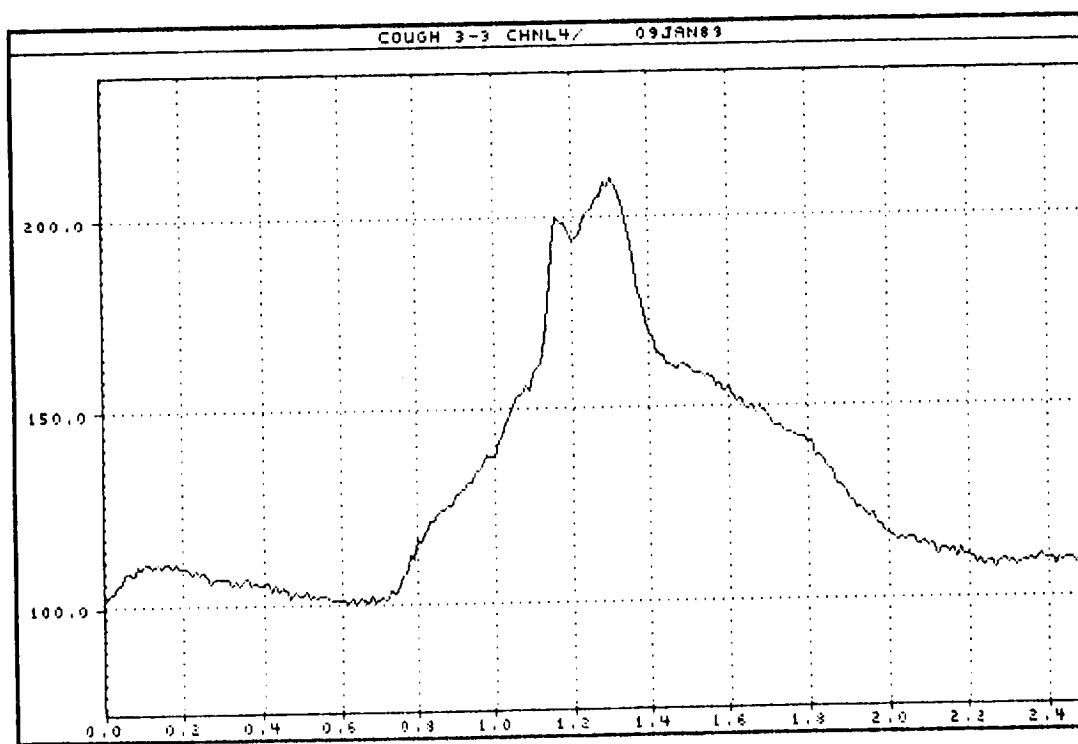


Figure 4b: Output Display, Format No. 2